REMARKS

Claim 1 is pending in the instant application. Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner suggests that while the specification is enabling for diagnosis of breast cancer, the specification does not reasonably provide enablement for diagnosis of prostate cancer or any gynecologic cancer; or for the diagnosis of metastasis, for the monitoring of change in stage, or the monitoring of onset of metastasis of prostate cancer or any gynecologic cancer. The Examiner suggests that the specification fails to establish that measuring levels of a polypeptide having the sequence of SEQ ID NO:2, or any other protein that is to be considered an ESBPII polypeptide, may be used for the detection of prostate cancer or any gynecologic cancer other than breast cancer.

Applicant respectfully traverses this rejection.

At the outset, it is respectfully pointed out that the pending claims are drawn to a method for detecting prostate cancer, ovarian cancer or uterine cancer in a patient. Thus, the Examiner's comments regarding enablement of diagnosis of prostate cancer or any gynecologic cancer, diagnosis of metastasis, monitoring of change in stage, and monitoring of onset of

metastasis of prostate cancer or any gynecologic cancer are not relevant to the instant claimed invention.

Further, in accordance with MPEP § 2164.04, in order to make a lack of enablement rejection, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. As stated by the court in *In re Marzocchi*, 439 F.2d 220,169 USPQ 367 (CCPA 1971), "[i]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Reasoning provided by the Examiner in the instant rejection is insufficient to meet this burden as none of the references cited by the Examiner are directed to the ESBPII protein.

In contrast, Applicant has provided detailed teachings in the specification regarding methodologies for detection of ESBPII including protein levels. See specifically page 12, line 29, through page 15, line 30. Further, Table 2 of the instant specification and pages 24 through 25 of the instant specification teach that ESBPII is overexpressed in 50% of uterine cancer samples tested, that median expression in the

ovary cancer samples is four times higher than the median expression in the normal ovary samples and that the median expression in the prostate cancer samples is higher than the median expression in the normal prostate samples. Thus, the sensitivity of this marker is actually greater than many useful cancer therapeutics and diagnostics that have been FDA approved and are commercially available. For example, Genentech's product Herceptin and its diagnostic counterpart, the HercepTest are very successful commercially. Yet many publications show the relevant gene, HER-2, is overexpressed in only 30% of breast cancer patients.

Further, Applicant is providing herewith a recent publication by Carter et al. (clinical Cancer Research 2003 9:7749-754) confirming Applicant's teaching that mRNA expression of ESBPII in ovarian and prostate cancer correlates with protein expression. As taught by Carter et al. in the Abstract, levels of lipophilin B antibody, indicative of protein expression, were seen not only in breast cancer but also in patients with prostate and ovarian cancer. Further, Carter et al. teach that the lipophilin B antibody levels are consistent with lipophilin B mRNA expression in these tumors. Lipophilin B is the same protein as BU101 (see reference BF of the IDS submitted April 29,

2002) and BU101 is the same protein as ESBPII (see page 5 of the instant specification).

This evidence establishes that there is no reason to doubt the objective truth of statements in the instant specification regarding use of ESBPII polypeptide levels as a diagnostic marker for prostate, uterine and ovarian cancer.

Thus, the instant specification, which provides detailed teachings of methods for making and using the instant claimed invention which correlate with the scope of claim 1 meets the enablement requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is respectfully requested in light of these remarks and the evidence submitted herewith.

Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Registration No. 38,350

Date: July 26, 2004

LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515